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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* THEODORE A. D. NOVAK and RONALD R. MANNA[1]

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Appeal 2015-002766
Application 11/582,746
Technology Center 3700

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Before ERIC B. GRIMES, JEFFREY N. FREDMAN, and
ULRIKE W. JENKS, *Administrative Patent Judges.*

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a medical device, which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

This application was the subject of an earlier appeal (Appeal 2012-000123, decided Jan. 18, 2013), in which the rejections were reversed. After the application was returned to the examining corps, the Examiner entered new rejections, Appellants amended the claims, and this appeal followed.

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[1] Appellants identify the Real Party in Interest as Misonix, Inc. (Br. 1.)

The Specification states that the

> invention relates to the treatment of wounds with ultrasound energy. The treatment contemplated by this invention includes fragmentation and emulsification of hard and soft tissue in a clinical environment while reducing unwanted heat and collateral tissue damage. In addition, the treatment includes method and apparatus for reducing pain at the operative site without drugs or other systemic treatment such as anesthesia. The present invention may be used in the treatment of wounds, warts or other lesions, wrinkles or skin disease.

(Spec. 1:5–11.)

Claims 1, 5–8, and 12–14 are on appeal. Claims 1 and 8 are the independent claims and read as follows (emphasis added):

> 1. A medical treatment device comprising:
> an ultrasonic probe;
> a transducer assembly operatively connected to said probe for mechanically vibrating said probe so that an operative tip of said probe oscillates at an ultrasonic frequency;
> a first electrical voltage source operatively connected to said transducer assembly for energizing same with an alternating voltage having an ultrasonic frequency;
> a second electrical voltage source operatively connected to said probe for feeding thereto a high-frequency alternating waveform of limited current and limited voltage to be conducted into a patient through said operative tip of said probe after placement of said operative tip into contact with the patient, said alternating waveform having a current and a voltage so limited as to prevent damage to organic tissues while stimulating nerves to reduce or suppress pain; and
> a synchronization circuit operatively connected to at least one of said first electrical voltage source and said second electrical voltage source and having an enabling circuit component including *a time delay element for enabling a commencing of probe vibration only after a predetermined time period has elapsed after a conducting of said alternating waveform into the patient has commenced.*

8. A medical treatment method comprising:

contacting a patient with an operative tip of an ultrasonic probe;

conducting a high-frequency alternating voltage into the patient through said operative tip of said probe while said operative tip is in contact with the patient, said alternating voltage having a current and a voltage so limited as to prevent damage to organic tissues while stimulating nerves to reduce or suppress pain; and

mechanically vibrating said probe so that said operative tip oscillates at an ultrasonic frequency while said operative tip is in contact with the patient,

*the mechanical vibrating of said probe commencing only after a predetermined time period has elapsed after a conducting of said alternating waveform into the patient has commenced.*

The claims stand rejected as follows:[2]

Claims 1, 5, and 7 under 35 U.S.C. § 103(a) as obvious based on Shimizu[3] and McHale[4] (Final Action 2);

Claims 6 and 13 under 35 U.S.C. § 103(a) as obvious based on Shimizu, McHale, Towe,[5] and Eggers[6] (Final Action 6, 11); and

Claims 8, 12, and 14 under 35 U.S.C. § 103(a) as obvious based on Shimizu, McHale, and Towe (Final Action 7–8).

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[2] The claims were also provisionally rejected for obviousness-type double patenting based on application 13/838,247. (Office Action mailed Dec. 11, 2013 ("Final Action"), pages 13–14.) However, USPTO records indicate that the '247 application went abandoned on Sept. 7, 2016. The provisional rejection is therefore moot.

[3] Shimizu, US 2008/0015473 A1, Jan. 17, 2008.

[4] McHale et al., US 2002/0193784 A1, Dec. 19, 2002.

[5] Towe et al., US 2006/0167500 A1, July 27, 2006.

[6] Eggers et al., US 6,896,672 B1, May 24, 2005.

I

The Examiner has rejected claims 1, 5, and 7 as obvious based on Shimizu and McHale. The Examiner has rejected claim 6 as obvious based on Shimizu, McHale, Towe, and Eggers. The same issue is dispositive for both rejections.

The Examiner finds that Shimizu discloses most of the limitations of claim 1 but "does not expressly disclose a processing means including a 'delay means' to 'automatically' commence probe vibration only after a predetermined time period has elapsed after a conducting of the alternating waveform." (Final Action 4.) The Examiner finds that McHale discloses a similar device and, "[i]n one embodiment, *McHale* uses a processor which is programmed to implement the operating parameters of the system (Paragraph [0033])." (*Id.* at 4–5.) The Examiner concludes that "the preprogrammed sequences as described by *McHale* must include a 'time delay element' (e.g. clock) in order to commence probe vibration only after a predetermined time period has elapsed after conducting the alternating waveform has commenced." (*Id.* at 5.)

Appellants argue, among other things, that "McHale et al. does not teach the use of a delay particularly as set forth in claim 1." (Br. 6.) Appellants argue that "[t]he Examiner's bald assertion that the McHale apparatus must have a delay element or must inherently introduce an incidental delay is hardly a teaching or suggestion of a specific delay element as set forth in appellant's claim 1." (*Id.*)

We agree with Appellants that the Examiner has not shown that the time delay element required by claim 1 would have been obvious based on

Shimizu and McHale. The Examiner reasons that "McHale teaches various pre-determined sequences of the ultrasound and electric field application which are carried out by a processing means with respect to the strength of energy or an amount of time," and includes "a processor which is programmed to implement the operating parameters of the system," and therefore must include the time delay element of claim 1. (Final Rej. 4–5.)

We conclude, however, that the cited passages of McHale do not support the Examiner's finding. McHale discloses that "sensitisation of nucleated cells by application of an electric field ('electrosensitisation') renders the cells susceptible to ablation using low intensity ultrasound and thereby provides a means of eliminating unwanted cells and tissues in the body." (McHale ¶ 9.) McHale discloses that the method can be carried out using an integrated system having an electrosensitization module, which includes an electric field generator, and an ultrasound module. (*Id.* ¶ 29.) McHale discloses that the system is preferably "in communication with a processor which can be programmed to implement operating parameters for the system." (*Id.* ¶ 33.)

McHale discloses that "[s]ingle or multiple applications of an electric field, as well as single or multiple applications of ultrasound are also possible, in any order and in any combination. . . . For example, the method can follow the sequence ES+US, ES+US, ES+US . . . (where ES is electro-sensitisation and US is ultrasound)." (*Id.* ¶ 115.) McHale also discloses that its device can be inserted into the body using a medical access device such as a catheter (*id.* ¶ 232), and that "[t]he medical access device can be in communication with a processor which can activate the electrosensitisation

module and/or ultrasound module and/or control the amount of time and the strength/frequency/power of energy delivered by the electrosensitisation module and/or ultrasound module." (*Id.* ¶ 233.)

The Examiner concludes that the description of the processor in McHale's paragraph 233, together with its statement in paragraph 33 that a processor can be programmed to implement the system's operating parameters, means that "the preprogrammed sequences as described by McHale must include a 'time delay element' (e.g. clock) in order to commence probe vibration only after a predetermined time period has elapsed after conducting the alternating waveform has commenced." (Final Action 5.) In other words, the Examiner finds that a "time delay element" is inherent in McHale's system.

We disagree.

> Where . . . the claimed and prior art products are identical or substantially identical . . . the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 U.S.C. § 102, on "prima facie obviousness" under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same.

*In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) (citations and footnote omitted).

However, "the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art" before the burden is shifted to the applicant to disprove the inherency. *Ex parte Skinner*, 2 USPQ2d 1788, 1789 (BPAI 1986).

Here, claim 1 requires the time delay element to "enabl[e] a commencing of probe vibration only after a predetermined time period has elapsed after a conducting of said alternating waveform into the patient has commenced." McHale discloses that its system can be operated to perform electrosensitization first, followed by ultrasound treatment. McHale also discloses that its system can include a processor that activates either the electrosensitization module or the ultrasound module, or both, and that the processor can also be programmed to "control the amount of time and the strength/frequency/power of energy delivered by the electrosensitisation module and/or ultrasound module." (McHale ¶ 233.)

The Examiner, however, has not provided an adequate basis for concluding that McHale's description of the capabilities of its system mean that the system *necessarily* includes an element that delays ultrasound treatment for a predetermined time after electrosensitization has commenced. The Examiner therefore has not shown that the time delay element required by claim 1 is disclosed in the cited references. The rejection of claim 1, and dependent claims 5 and 7, as obvious based on Shimizu and McHale is reversed.

Claim 6 also depends from claim 1. The Examiner has rejected claim 6 as obvious based on Shimizu, McHale, Towe, and Eggers. (Final Action 6.) The Examiner cites Towe and Eggers only for their disclosure of reducing pain using high frequency (e.g., 100 MHz) current. (*Id.* at 7.) Thus, the Examiner has not pointed to any disclosure in Towe or Eggers that makes up for the deficiency of McHale discussed above. We therefore reverse the rejection of claim 6.

II

The Examiner has rejected claims 8, 12, and 14 as obvious based on Shimizu, McHale, and Towe. The Examiner rejected claim 13 as obvious based on Shimizu, McHale, Towe, and Eggers. The same issue is dispositive for both rejections.

Claim 8 is directed to a method that includes mechanically vibrating the tip of a probe at an ultrasound frequency, "the mechanical vibrating of said probe commencing only after a predetermined time period has elapsed after a conducting of said alternating waveform into the patient has commenced." (Claim 8.)

The Examiner relies on the same reasoning as in the rejection of claim 1 to conclude that McHale's system "must include a 'time delay element' (e.g. clock) in order to commence probe vibration only after a predetermined time period has elapsed after conducting the alternating waveform has commenced." (Final Action 10.) For the reasons discussed above with respect to claim 1, however, we conclude that the evidence and reasoning of record do not support the finding that McHale's system necessarily includes a time delay element that carries out the recited function. We therefore reverse the rejections of claims 8 and 12–14.

SUMMARY

We reverse all of the rejections on appeal.

REVERSED